117TH CONGRESS
2D SESSION

S. _____

To require guidance on extending expiration dates for certain drugs, and for other purposes.

IN THE SENATE OF THE UNITED STATES

Mr. CARDIN introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To require guidance on extending expiration dates for certain drugs, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Drug Shortages Shelf Life Extension Act''.

SEC. 2. EXTENDING EXPIRATION DATES FOR CERTAIN DRUGS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Sec-

retary'') shall issue draft guidance, or revise existing guidance, to address recommendations for sponsors of applications under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) regarding—

(1) the submission of stability testing data in such applications; and

(2) establishing in the labeling of drugs the longest feasible expiration date supported by such data, taking into consideration how extended expiration dates may help prevent or mitigate drug shortages.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, and again 2 years thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes—

(1) the number of drugs for which the Secretary has requested the manufacturer make a labeling change regarding the expiration date; and

(2) for each drug for which the Secretary has requested a labeling change with respect to the expiration date, information regarding the circumstances of such request, including—

(A) the name and dose of such drug;

(B) the rationale for the request;

(C) whether the drug, at the time of the request, was listed on the drug shortage list under section 506E of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356e), or was at risk of shortage;

(D) whether the request was made during a public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d); and

(E) whether the manufacturer made the requested change by the requested date, and for instances where the manufacturer does not make the requested change, the manufacturer's justification for not making the change, if the manufacturer agrees to provide such justification for inclusion in the report.